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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,737	02/03/2004	David S. Burt	021989-000411US	4042

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,737	BURT ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/24/05, 7/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received February 3, 2004.

Priority

Acknowledgment is made for priority to a DIV application, 09/788,280, which is a US Patent 6,743,9000 B2.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed August 24, 2005 and July 22, 2005 are attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to elicit an immune response comprising administering an influenza vaccine comprising hemagglutinin antigen, does not reasonably provide enablement for a method comprising administering an influenza vaccine comprising any one influenza antigen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The claims encompass using any influenza antigen in the influenza vaccine formulation. The instant specification provides an example of using an influenza vaccine comprising hemagglutinin (HA) formulated with proteasomes, in the method of eliciting an immune response against influenza and treating infection in an animal. However the instant specification does not provide examples of using an influenza vaccine comprising influenza antigens, other than hemagglutinin (HA). The instant specification is not enabling for practicing the method to elicit an immune response or the method of treating infection in an animal using an influenza vaccine comprising any one influenza antigen or any other viral antigen other than influenza hemagglutinin (HA).

Crowe et al. (Identification of protective and non-protective T cell epitopes in influenza, 2006, Vol. 24, p. 452-456) demonstrated that the capability of different influenza antigens to elicit protective immune responses varies and depends on the source of the antigen. The antigens

derived from influenza PA, HA, and M1 proteins had poor protective efficacy as evidenced by increased viral titers in vaccinated mice subsequently challenged with the virus. However, the immune responses, generated in mice vaccinated with influenza antigens derived from NP and BP1 proteins contributed to significant viral clearance in challenged mice. Thus the ordinary artisan would be unable to predict the success of an immunization method using influenza vaccine comprising any one influenza antigen without conducting extensive experimentation.

In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with a corresponding lack of scientific data and working embodiments regarding the method for eliciting an immune response and the method for treating the infection, that one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately extrapolate whether influenza vaccine comprising any one influenza antigen could be successfully used in the claimed methods.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Levi et al. (Vaccine, 1995, IDS of 7/22/2005).

The instant invention is drawn to a method for eliciting an immune response against influenza in a subject, and a method for treating infection in an animal comprising administering influenza vaccine of viral antigen formulated with proteosome preparation, wherein formulation ratio is greater than 1:1. The vaccine is formulated in the presence of detergent, which is removed from the preparation by diafiltration or ultrafiltration or by using dialysis (see Example 3), and the vaccine is formulated in the substantial absence of detergent. The viral antigen, in the method for eliciting an immune response is influenza antigen and the subject is human. The vaccine is multivalent, and it is administered by intranasal and parenteral route.

Levi et al. disclose a method for eliciting an immune response against influenza, and a method for treating infection in an animal comprising administering formulation of influenza antigen and proteosome, wherein the antigen and proteosome ratio is 4:1 and wherein the formulation is prepared in the presence of detergent, which is subsequently removed from the preparation by dialysis (see the entire document, particularly Results, Figures 1, 2, and 3 and Preparation of proteosome-peptide vesicles). The viral antigen in Levi's preparation is derived from influenza NP and HA proteins. Levi et al. disclose intranasal (which is also a parenteral administration route) administration of the preparation in mice (see Immunization and infection procedures) and discuss application of the influenza antigen-proteosome preparation for human use (see Discussion). The generation of immune responses is shown in Figure 1 and Figure 2. Figure 3 shows the protective effect of a multivalent formulation of a proteosomes and influenza antigen against challenge with influenza virus. Thus, the instant invention is anticipated by Levi et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levi et al. (Vaccine, 1995, IDS of 7/22/2005) as applied to claims 1-4, 6-12 above, and further in view of Fynan et al. (International Journal of Immunopharmacology, 1995).

The instant invention is drawn to a method for eliciting an immune response against influenza in a subject, and a method for treating infection in an animal comprising administering influenza vaccine of viral antigen formulated with proteosome preparation, wherein formulation ratio is grater than 1:1. The vaccine is formulated in the presence of detergent, which is removed from the preparation by diafiltration or ultrafiltration or by using dialysis (see Example 3), and the vaccine is formulated in the substantial absence of detergent. The viral antigen, in the method for eliciting an immune response is influenza antigen and the subject is human. The vaccine is administered intramuscularly.

Levi et al. teaches a method for eliciting an immune response against influenza, in an animal comprising administering formulation of influenza antigen and proteosome as discussed above. Levi et al. does not teach intramuscular administration of the influenza vaccine. Fynan et al. overcomes this deficiency by teaching intramuscular administration of influenza vaccine.

It would have been obvious to the person of ordinary skill in the art to administer influenza vaccine by intramuscular route. One of the ordinary skill in the art would have been

motivated to administer Levi's influenza vaccine by intramuscular route as taught by Fynan et al. because Fynan et al. teaches that intramuscular administration of influenza vaccine resulted in generation of the highest level of protective protective immunity against influenza virus as compared to subcutaneous or intradermal administration (see page 81, right column)

One would have had a reasonable expectation of success to elicit a protective immune response against influenza virus by intramuscular administration of influenza vaccine because Fynan et al. has shown that protective immune responses can be generated by this administration route.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner
9/21/06

Stacy B. Chen 9/21/06
STACY B. CHEN
PRIMARY EXAMINER